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| | First Named Inventor | Pieter Cornelis LANGEVELD | |
| | Art Unit | 1653 | |
| | Examiner Name | R. Kosson | |
| Total Number of Pages in This Submission | 12 | Attorney Docket Number | 246152016900 |

ENCLOSURES (Check all that apply)

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| <input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input checked="" type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) Amended Appeal Brief including Appendix A (11 pages) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard |
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|--------------|-------------------------|----------|--------|
| Firm Name | MORRISON & FOERSTER LLP | | |
| Signature | | | |
| Printed name | Carolyn A. Favorito | | |
| Date | April 28, 2006 | Reg. No. | 39,183 |

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Dated: April 28, 2006

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(Germaine Sarda)

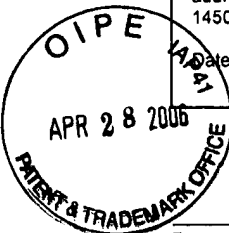
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Dated: April 28, 2006

Signature:

Germane Sarda
(Germane Sarda)

Docket No.: 246152016900
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Pieter Cornelis LANGEVELD et al.

Application No.: 10/089,874

Confirmation No.: 1426

Filed: (Int'l) October 3, 2000

Art Unit: 1653

For: METHOD FOR THE DETECTION OF
ANTIMICROBIAL RESIDUES

Examiner: R. Kosson

AMENDED APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants submit this Amended Appeal Brief in response to the Notification of Non-Compliant Appeal Brief mailed March 28, 2006 for which a response is due April 28, 2006. The Office indicated that sections numbered 8 and 9 were missing from the Appeal Brief. As the original Appeal Brief contained section VIII, it is believed that the Office intended to indicate that sections IX and X were missing. This Amended Appeal Brief indicates in numbered sections IX and X that no Evidence or Related Proceedings Appendices are included with this Amended Appeal Brief.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1205:

- I. Real Party In Interest
- II Related Appeals and Interferences

| | |
|------------|---|
| III. | Status of Claims |
| IV. | Status of Amendments |
| V. | Summary of Claimed Subject Matter |
| VI. | Grounds of Rejection to be Reviewed on Appeal |
| VII. | Argument |
| VIII. | Claims Appendix |
| Appendix A | Claims |

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is:

DSM N.V.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 13 claims pending in this application.

B. Current Status of Claims

1. Claims canceled: 11-13
2. Claims withdrawn from consideration but not canceled: none
3. Claims pending: 1-10, 14-16
4. Claims allowed: none
5. Claims rejected: 1-10, 14-16

C. Claims On Appeal

The claims on appeal are claims 1-10, 14-16

IV. STATUS OF AMENDMENTS

Appellant filed an Amendment After Final Rejection on April 25, 2005. The Examiner responded to the Amendment After Final Rejection in an Advisory Action mailed May 17, 2005. In the Advisory Action, the Examiner indicated that Appellants' proposed amendments to claims 1-10 and 14-16 would not be entered.

Accordingly, the claims enclosed herein as Appendix A do not incorporate the amendments to claims 1-10 and 14-16 as indicated in the paper filed. However, the claims in Appendix A do incorporate the amendments indicated in the paper filed by Applicant on January 18, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention relates to detecting whether a sample, such as a food product, contains an antimicrobial residue, such as a residue from an antibiotic administered to an animal. Please see page 1, paragraphs 1 and 2 of the present specification. According to the presently claimed invention, the sample, such as a food product, is contacted with a test, such as one containing a microbe, that can determine whether such an antimicrobial residue is present in the sample. Please see page 4, lines 10-22, the paragraph bridging pages 4 and 5, and the Examples of the present specification. Thereafter, any disturbing compounds, such as blood pigments, are inactivated which otherwise would interfere with the test and lead to false positive results. Please see, *e.g.*, Example 1, page 10, lines 24-26 and page 11, lines 1-2. Unlike some prior art, the claimed inactivating step is conducted on the *sample and test*, in contrast to the sample without the test, as in some prior art methods. Please see page 31, last two paragraphs of specification. The claimed inactivating step may take place, for example, by heating (please see claims 5 and 6) or by contacting a sample with a thickening agent (please see page 4, lines 3-5 of the present specification, claim 2, and Example 6, showing that inactivating temperatures are not required to

accomplish the inactivating step). The inactivation depends on various conditions such as type of sample, condition of sample, type of test, and type of microorganism used in the test. Please see page 7, last paragraph of the present specification. Following the claimed inactivating step, the sample and test are incubated to determine whether microbial growth from the test occurs. Please see page 4, lines 1-2. If an antimicrobial residue is present, then microbial growth will not occur.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether obviousness-type double patenting rejection should be withdrawn in view of terminal disclaimer filed.

2. Whether claims 1-10 and 14-16 are anticipated under 35 U.S.C. § 102(b) by Charm (U.S. Patent No. 5,354,663, "Charm") when Charm does not disclose an inactivating step performed on a contacted sample *and test* as claimed.

3. Whether claims 1-3, 5, 8-10, and 16 are anticipated under 35 U.S.C. § 102(b) by Gist-Brocades (EP 0 005 891, "Gist-Brocades"), which does not disclose the inactivating step as claimed.

4. Whether claims 1-3, 5-6, 8-10, and 16 are anticipated under 35 U.S.C. § 102(b) by Laméris (U.S. 3,941,658, "Laméris"), which does not explicitly disclose an inactivating step *followed by* an incubating step as claimed.

5. Whether claims 1-10 and 14-16 are obvious under 35 U.S.C. § 103(a) over Gist-Brocades in view of Charm (both referenced above).

VII. ARGUMENT

1. Obviousness-Type Double Patenting Rejection.

A terminal disclaimer was filed April 25, 2005 and was acknowledged in the Advisory Action mailed May 17, 2005; however, this rejection was not withdrawn. Thus, appellants respectfully request reversal of this rejection.

2. Anticipation Over Charm.

Claim 1 defines the inactivating step (Step (ii)) as “followed by” the incubating step (Step (iii)). The inactivating step is performed on both the *sample* and *test*. In contrast, Charm teaches inactivating the sample alone (please see column 3, lines 33-35) and “thereafter” (please see column 3, line 46) heating the inactivated sample having BST spores added thereto (please see column 3, lines 47-48). In response to this argument, the Examiner alleged that the order of the steps is not recited in the rejected claims. Please see page 3 of the Office action mailed February 25, 2005. However, the steps at least implicitly follow the order, because Step (i) includes contacting the sample with a test, and the second step involves inactivating the contacted sample and test and this step is explicitly followed by Step (iii), which requires incubating the contacted sample and test. It is respectfully submitted that this reference teaches away from inactivating natural disturbing compounds in the contacted sample and test because this reference teaches inactivation of the sample alone. The claimed invention, therefore, is not disclosed in Charm and, thus, reversal of this rejection is respectfully requested.

3. Anticipation over Gist-Brocades.

Example 1 (page 10, lines 13-26 of the present application), among other Examples, describes the Gist-Brocades reference. False positive results were received on a sample tested according to the Gist-Brocades method. Gist-Brocades does not disclose an inactivating step. However, the Examiner appears to take notice that “heating the sample and test together at 60°C for 1½ to 4 hours both destroys any natural disturbing compound present in the sample and allows for incubation of the test organism.” The comparative test results in Example 1 of the present application belie such a conclusion that any natural disturbing compounds inherently are destroyed

before incubation by virtue of the false positive results reported in Example 1. Thus, the inactivation step does not necessarily occur. It is well-settled that “[i]nherency may not be established by probabilities or possibilities.” Please see *In re Oelrich*, 666 F2d 578, 212 USPQ 323, (CCPA 1981), a copy of which is enclosed herewith. The Examiner has not established anticipation because all of the steps of the claimed method are not found explicitly or inherently in the Gist-Brocades reference. Thus, appellants respectfully request reversal of this rejection.

4. Anticipation over Laméris.

Similarly, Laméris does not disclose an incubation step. Laméris discloses that the mixture of the sample and test is heated to about 55°C to 70°C and incubated for about 1½ to four hours, which the Examiner alleges without support that such “destroys any natural disturbing compound present in the sample and allows for incubation of the test organism.” The Examiner further alleges that the claimed invention does not require that the inactivation temperature be different than the incubation temperature. However, Laméris does not disclose that inactivation will necessarily occur under the particular conditions disclosed therein before incubation occurs. Thus, assuming for the sake of argument that Laméris anticipates the present claims, then the inactivating step must be inherent in the disclosure.

The present specification, on page 7, lines 27-35, discloses that the time and temperature required for the inactivating step is dependent on the type of sample, the condition of the sample, the type of test, or the microorganism used in the test. Laméris’ cited conditions will not necessarily inactivate any natural disturbing compound. The Examiner has not provided evidence or established that, under Laméris’ particular conditions, inactivation will necessarily take place.

During a telephonic interview, the Examiner pointed to the recitation of 70°C in present claim 6 as suggesting that inactivation will take place at 70°C for any type of sample under any conditions, for any type of test for any microorganism. This logic is flawed in that claim 1 necessarily includes an inactivating step and, thus, the conditions must be appropriate at, for example, 70°C for the inactivating step to take place. The Examiner appears to suggest, therefore, that the disclosure of 70°C in Laméris *may* inactivate any natural disturbing compound under

certain conditions. Of course, the possibility that inactivation may take place is not the appropriate standard for determining inherency. Thus, it cannot be said that Laméris' disclosure of 70°C inherently discloses the explicitly-claimed inactivating step.

Moreover, Laméris does not disclose that any naturally disturbing compounds must be inactivated *before* microbial growth may occur and, thus, this sequence must necessarily be inherent to support a proper anticipation rejection. The Examiner provided no evidence or reasoned argument that Laméris' disclosed heating step will necessarily inactivate disturbing compounds before microbial growth occurs, and thus neither inherency nor anticipation have been established.

For these further reasons, reversal of this rejection is respectfully requested.

5. Obviousness over Gist-Brocades in View of Charm

The arguments above with respect to Gist-Brocades and Charm are incorporated here. Based on these arguments alone, it is respectfully submitted that all of the claimed elements are not disclosed in the cited references and, thus, *prima facie* obviousness has not been established.

Further, the Examiner alleges on page 6 of the Office action mailed February 25, 2005 that Charm discloses heating the sample to 80°C - 85°C (which is Charm's inactivation step) and then heating the combination of the sample and test to 100°C inactivates any natural disturbing compound. However, according to Charm as described above, the natural disturbing compounds were already inactivated during the first heating step and, thus, Charm does not disclose the step of inactivating any natural disturbing compounds in the *sample and test* as claimed. Moreover, Charm or Gist-Brocades provides no reasonable expectation that any natural disturbing compound would be successfully inactivated by heating the sample and test to 100°C.

Further, MPEP § 2144.04(b) states that omission of a step and retention of its function is an indicum of unobviousness. The method of the invention makes it feasible to read a test without a pre-incubation step as described in Charm. (Please see the present specification at page 3, lines 8-13; page 14, lines 12-13; and page 15, lines 11-12.)

The Examiner has made a confusing reference to the inactivation of natural disturbing compounds in Gist-Brocades and Laméris on page 6 of the Office action, but the rejection was only based on Gist-Brocades. Thus, although not explicitly stated, the Examiner's position appears to rely on Charm's disclosure of heating a sample and test which do not contain any natural inhibiting compounds to about 100°C as motivation to raise Gist-Brocades' *incubation* temperature from 60°C to 100°C. However, a skilled artisan would not be motivated to depart from optimal incubation temperatures such as about 60°C to a much warmer 100°C temperature. Also, of course, there is no motivation in Charm to modify the incubation temperature of a mixture containing a sample, a test, and any natural disturbing compounds.

Thus, the Examiner has not established *prima facie* obviousness in accordance with MPEP § 2143 because the references do not disclose all of the claimed steps, the Examiner provided no motivation to combine the references, and a skilled artisan would not expect such a combination to be successful. Thus, reversal of this rejection is respectfully requested.

Even if for the sake of argument *prima facie* obviousness was established, the Examiner did not consider evidence of advantageous results as found in the Examples of the present specification on pages 10-16. These examples specifically compare the Gist-Brocades methods with the methods of the invention. False positive results were found using the Gist-Brocades methods which did not occur in methods conducted in accordance with the inventive process. Please see page 10, lines 24-26; the sentence bridging pages 10-11; page 11, lines 13-14 and 22-27; page 12, lines 12-15; and page 13, lines 6-7 and 16-18. For this reason, even if *prima facie* obviousness was established, the evidence disclosed in the present application overcomes such a showing. Thus, reversal of this rejection is respectfully requested.

VIII. CLAIMS APPENDIX

A copy of the claims involved in the present appeal is attached hereto as Appendix A. As indicated above, the claims in Appendix A do include the amendments filed by Applicant on January 18, 2005, and do not include the amendment(s) filed on April 25, 2005.

IX. EVIDENCE APPENDIX

This Brief contains no Evidence Appendix.

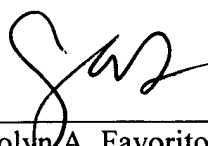
X. RELATED PROCEEDINGS APPENDIX

This Brief contains no Related Proceedings Appendix.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 246152016900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: April 28, 2006

Respectfully submitted,

By 

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APPENDIX A

Claims Involved in the Appeal of Application Serial No. 10/089,874

1. (previously presented): A process for determining the presence or absence of an antimicrobial residue in a sample, which process comprises:

(i) contacting the sample with a test suitable for determining the presence or absence of an antimicrobial residue in the sample;

(ii) inactivating any natural disturbing compound, which is capable of inhibiting the test leading to a false positive result absent said inactivating step, present in the contacted sample and test; followed by

(iii) incubating the contacted sample and test, to determine whether microbial growth occurs,

whereby the absence of microbial growth indicates the presence of at least one antimicrobial residue.

2. (previously presented): A process according to claim 1, which further includes contacting said sample with a thickening agent.

3. (previously presented): A process according to claim 2, wherein the thickening agent is a polysaccharide or a protein.

4. (previously presented): A process according to claim 3, wherein the thickening agent is methyl cellulose or bovine albumin.

5. (previously presented): A process according to claim 1, wherein step (ii) comprises heating the contacted sample and test for a sufficient time interval to inactivate natural disturbing substances present in the sample.

6. (previously presented): A process according to claim 5, wherein said heating is to a temperature of from 70°C to 100°C.

7. (previously presented): A process according to claim 5, wherein said heating is for from 2 to 20 minutes.

8. (previously presented): A process according to claim 1, wherein the sample is a foodstuff, an animal body fluid, an animal tissue or an extract thereof.

9. (previously presented): A process according to claim 8, wherein the body fluid is blood, urine, pre-urine, milk, or meat juice.

10. (previously presented): A process according to claim 8, wherein the animal tissue or an extract thereof is muscle, heart, liver or kidney or an extract thereof.

11-13. (canceled)

14. (previously presented): A process according to claim 5, wherein said heating is to a temperature of from 75°C to 85°C.

15. (previously presented): A process according to claim 5, wherein said heating is for from 10 to 15 minutes.

16. (previously presented): A process according to claim 2, wherein the sample is a foodstuff, an animal body fluid, an animal tissue or an extract thereof.